Scott D. Ballin, JD
Health Policy Consultant
6220 30th Street NW Washington DC 20015
Tel: 202 686-8898 Fax: 202 244-0698

February 15, 2012

TO: Tobacco Products Scientific Advisory Committee

SUBJECT: Observations and comments on draft report on DTP's

Attention: Caryn Cohen, MS
Center for Tobacco Products
Food and Drug Administration
9200 Corporate Blvd
Rockville, MD 20850

I cannot help but conclude that the findings and recommendations contained in the TPSAC draft report on dissolvable tobacco products (DTPs) only reinforces the views and suggestions I have expressed in a number of white papers and presentations --- namely that what is needed **is a more coherent, balanced and rational regulatory approach governing all tobacco, nicotine and alternative products.**

The public and users of the spectrum of tobacco, nicotine and alternative products will continue to remain confused and uninformed until they are provided full, complete, truthful and understandable information about the risks, relative risks, benefits and intended uses of the growing spectrum of products. That should be a major focus for the TPSAC, FDA and the private sector in the coming months.

It is once again clear that the constraining nature of the statutory mandate placed obligations on the FDA and TPSAC that limited the ability to have a broader and more in-depth discussion in what is a dynamically changing environment. I think that the Institute of Medicine in its efforts to try and meet another statutorily constraining mandate in looking at scientific standards for MRTPs)modified risk tobacco products) was correct when it said it its summary:

> **" The committee was particularly wary of making "perishable" recommendations that may lose relevance as time passes and scientific methods and technologies evolve'**. (IOM Report, Scientific Standards for Studies on MRTPs, Summary, page 3, December 2012)

By limiting discussion because of the mandate, TPSAC unfortunately subjects itself to having to make potentially 'perishable recommendations' that may have already lost or will lose their relevance. A few examples of the limitations placed on the Committee make my point:

- Chairman Samet had to routinely remind the Committee of the mandated 'charge'. This is not a criticism of the Chairman but rather an example and indication of the limitations that were placed on the discussion as part of the 'charge' -- a charge that was given to FDA almost 3 years ago.

- The dismissal of the 'Swedish experience'- which actually might have at least educated Committee members on how we might go about developing a prospective **'American experience'** that might include better and more comprehensive labeling, marketing, educational programs, as well as making science - based significantly lower risk products more consumer acceptable for not just dissolvables but all tobacco, nicotine and alternative products.

- The Committee's refrain from looking at the NRT market place which has many products that are comparable to some of the DTPs (lozenges in particular). The NRT products come in assorted flavors like fruit chill, lime and mocha. They are advertised on television and in print. They come in eye-catching packaging and are sold over the counter. The packaging is in most cases less burdensome in opening than some of the DTP's and they are easily concealable. Even government sponsored websites on 'Quitting' refers to the lozenges as having a 'hard candy' appearance and noting that not all NRT works the same for all users. The ability to quit varies and in many cases there is dual use or even total relapse. And let us not forget that these products contain nicotine that is derived from tobacco. The differing risk profiles between NRT and some of the DTP's may be in fact be very narrow - especially when compared with the toxic combustible cigarette.

I hope that as these congressionally mandated obligations are met and dispensed with that TPSAC and FDA will begin to broaden its focus of discussion. This is a "New Era" and one that will require that we do a better job of considering what a product is and is not rather than who the manufacturer is.

The FDA's upcoming scientific workshops at the end of February and April represent, in my view, the kind of work and discussions that should have **preceded** any discussions about DTPs (and of course all tobacco, nicotine, and alternative products). Both the public and private sectors should be talking about how best to meet and educate the public and consumers about the spectrum of products and move away from the public relations rhetoric of the decades old 'tobacco wars'.

Respectfully Submitted,

_____

Scott D. Ballin, JD